APT/CPW

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Marlies REGIERT ET AL. - 2

SERIAL NO.: 10/712,703 EXAMINER: ISSAC, ROY P.

FILED: NOVEMBER 12, 2003 GROUP: 1623

TITLE: COSMETIC COMPOSITION COMPRISING A COMPLEX OF CYCLODEXTRIN AND VITAMIN F

COVER LETTER ENCLOSING BRIEF ON APPEAL

MAIL STOP APPEAL BRIEF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Enclosed herewith for filing is a Brief on Appeal and fee. The Commissioner of Patents is hereby authorized to charge any underpayment or credit any overpayment to Deposit Account No. 03-2468.

Respectfully submitted,
MARLIES REGIERT ET AL

COLLARD & ROE, P.C.
1077 Northern Boulevard
Roslyn, New York 11576
(516) 365-9802

Elizabeth Collard Richter, Reg.No.35,103
Attorney for Applicant

ECR:cmm
Enclosure: Brief on Appeal and Check for $510.00

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on February 1, 2008.

Amy Klein
Amy Klein

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Marlies REGIERT ET AL. - 2

SERIAL NO.: 10/712,703 EXAMINER: ISSAC, ROY P.

FILED: NOVEMBER 12, 2003 GROUP: 1623

TITLE: COSMETIC COMPOSITION COMPRISING A COMPLEX OF CYCLODEXTRIN AND VITAMIN F

BRIEF ON APPEAL

MAIL STOP APPEAL BRIEF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 2313-1450

Dear Sir:

In accordance with the provisions of Rule 192(c), the following items under appropriate headings are provided:

(1) REAL PARTY IN INTEREST:

The real party in interest is Wacker-Chemie GmbH, the assignee of the patent application identified in the caption above.

(2) RELATED APPEALS AND INTERFERENCES:

There are no other appeals or interferences known to Appellant, the Appellant's legal representative, or assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) STATUS OF CLAIMS:

Claims 1 and 9 are in the application and have been rejected.

((4) STATUS OF AMENDMENTS:

Claims 1 and 9 stand rejected under 35 USC §103 as being unpatentable over Bruzzese et al. (EP 0 470 452) in view of Schlenk et al. (J. Am. Chem. Soc., 83, 2312-2320; 1961) and further in view of Koulbanis (US 4,393,043).

No amendments were filed after the Office Action dated September 25, 2007. The remarks filed on November 5 have been considered, but the additional evidence presented therewith has not been entered.

(5) SUMMARY OF CLAIMED SUBJECT MATTER:

The present invention is described below with reference to the page and line numbers from the specification. Such references are for illustration only and are not intended to limit the claims. The drawings show stability data and do not show structural or process features of the claims, so no reference to drawing reference numbers is given here.

The present invention as claimed in independent claim 1 relates to a cosmetic or dermatological preparation or formulation comprising vitamin F, wherein the vitamin F is an essential fatty acid and is present in the form of a complex with alpha-cyclodextrin. (page 8, lines 1-4) The essential fatty acid and alpha-cyclodextrin are present in the complex in a ratio of:

3 mol of alpha-cyclodextrin: 1 mol of an essential fatty acid,

4 mol of alpha-cyclodextrin: 1 mol of an essential fatty acid,

or a mixture of these complexes (page 10, lines 16-19).

The process of the invention as claimed in dependent claim 9, is a process for preparing a preparation as claimed in claim 1, comprising

dispersing a complex of vitamin F and alpha-cyclodextrin in water to form a dispersion; and

then mixing the dispersion into a lipophilic part of an emulsion (p. 13, lines 15-17).

(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL:

Whether the rejection of claims 1 and 9 under 35 U.S.C. §103 as being unpatentable over Bruzzese in view of Shlenk et al. and

further in view of Koulbanis, respectively, is proper, or whether this rejection should be reversed.

(7) ARGUMENT

The above-defined issue is believed to be in error and should be reversed for the following reasons:

The arguments of the Examiner are based on the assumption that a polyunsaturated fatty acid (PUFA) is the same as an essential fatty acid. This is not correct. A polyunsaturated fatty acid is a fatty acid in which more than one double bond exists within the representative molecule. That is, the molecule has two or more points on its structure capable of supporting hydrogen atoms not currently part of the structure.

Polyunsaturated fatty acids can assume a cis or trans conformation depending on the geometry of the double bond. Essential fatty acids (EFAs) are fatty acids that cannot be constructed within an organism from other components by any known chemical pathways; and therefore must be obtained from the diet. The term refers to those involved in biological processes, and not fatty acids which may just play a role as fuel. As many of the compounds created from essential fatty acids can be taken directly in the diet, it is possible that the amounts required in

the diet (if any) are overestimated. It is also possible that they can be underestimated, as organisms can still survive in non-ideal, malnourished conditions.

There are two families of EFAs: ω-3 (or omega-3 or n-3) and ω-6 (omega-6, n-6). Fats from each of these families are essential, as the body can convert one omega-3 to another omega-3, for example, but cannot create an omega-3 from scratch. They were originally designated as Vitamin F when they were discovered as essential nutrients in 1923. In 1930, work by Burr, Burr and Miller showed that they are better classified with the fats than with the vitamins. Essential fatty acids are a clearly defined subgroup of polyunsaturated fatty acids. None of the references cited by the Examiner discloses an essential fatty acid as shown in the following:

The argumentation of the Examiner on page 3 of the Final office action and on page 6 of the Final office action, that Bruzzese et al. discloses essential fatty acids in example 6 or in examples 1, 4, 5, 6, 7, 8, 9, and 10; columns 4 - 7 is wrong. Bruzzese discloses <u>solely</u> polyunsaturated fatty acids, but none of these polyunsaturated fatty acids is an essential fatty acid.

The state of the art discloses 2:1 or 1:1 PUFA/CD complexes, but does not disclose 2:1 or 1:1 EFA/CD complexes. The present application solely claims 3:1 and 4:1 EFA/CD complexes. Therefore, the argumentation of the Examiner based on 2:1 or 1:1 EFA/CD complexes as state of the art, that it is the burden of the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art is unjustified, because no such state of the art exists.

Schlenk discloses that fatty acids with 17 and higher carbons produce 1:3 complexes with CD. The Examiner argues that the combination of Schlenk and Bruzzese make the present invention obvious because one of ordinary skill in the art would have been motivated to use alpha CD to form a complex with essential fatty acids because the complexation increases solubility and alpha CD forms higher order complexes with longer chain fatty acids. This argumentation is not correct, because the aim of the present application is to achieve complexes with an increased stability and not complexes with an increased solubility of the complex. Schlenk discloses saturated fatty acids, whereas the present application is only related to essential fatty acids. Saturated fatty acids are per se stable, whereas essential fatty acids are not stable as discussed in the present application. Therefore, the problem to be solved by the

3:1 and 4:1 complexes does not exist for the materials complexed by Schlenk, and a combination of Schlenk and Bruzzese cannot lead to a solution for the problem to be solved by the present application. Moreover, even if combined, such a combination does not lead to the present invention because Bruzzese does not disclose the complexation of EFAs, but only of PUFAs. A teaching which results in 1:1 and 2:1 complexes of PUFAs with CDs cannot anticipate a teaching which results in 3:1 and 4:1 complexes of EFAs with CD.

Koulbanis discloses the use of Vitamin F for the preparation of cosmetics, and further discloses the problem of vitamin F with oxidation. Thus, Koulbanis describes the state of the art for the use of Vit. F in cosmetics. The problems of this state of the art are resolved by the present application, and none of the cited references suggest that a complex of alpha CD with an essential fatty acid would solve these problems. Thus, the claimed solution is not rendered obvious by combination of Koulbanis with Bruzzese because Bruzzese does not disclose EFAs at all.

In fact, the claimed complexes significantly improve the usability of Vitamin F in cosmetics, in contrast to Koulbanis.

Enclosed as Appendix A, which was also enclosed in the response to the Final Office Action, is a Power Point presentation which shows:

- on slide 9: a scheme is given which shows a model which illuminates why only 3:1 and 4:1 complexes work well and why 1:1 and 2:1 complexes have only a very minor effect (only 3 or 4 CD cavities cover the long EFA molecule sufficiently to result in a positive effect).

- on slide 13: the thermostability of different complexes of linoleic acid (An EFA/Vitamin F) with CDs.

- on slide 14: the UV stability of a complexed (invention) and an uncomplexed (state of the art) linoleic acid

- on slide 17: the UV stability of complexed (invention) and uncomplexed (state of the art) linoleic acid in a cream.

- on slide 18: the long-term stability of 1% linoleic acid as 4:1 complex (invention) and uncomplexed (state of the art) linoleic acid in a cream.

-on slide 19: the degradation behavior of complexed and uncomplexed linoleic acid is shown.

-on slide 20: the light stability of of 1% linoleic acid as 4:1 complex (invention) and uncomplexed (state of the art) linoleic acid in color cosmetics is shown.

In summary, the claimed invention is patentable over the cited references, because none of the references refer to a complex with an essential fatty acid with alpha cyclodextrin.

Accordingly, Applicants submit that claims 1 and 9 are patentable over the cited references, taken either singly or in combination. Reversal of the Examiner's rejection of the claims is respectfully requsted.

Respectfully submitted,
MARLIES REGIERT ET AL

Elizabeth Collard Richter, Reg.No.35,103
Attorney for Applicants

COLLARD & ROE, P.C.
1077 Northern Boulevard
Roslyn, New York 11576
(516) 365-9802
ECR:cmm

Enclosure: Appendices A-C

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Assistant Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 1, 2008.

Amy Klein

APPENDIX A

(9) APPENDIX

The Appealed claims are as follows:

1. A cosmetic or dermatological preparation or formulation comprising

vitamin F, wherein the vitamin F is an essential fatty acid and is present in the form of a complex with alpha-cyclodextrin, and

wherein the essential fatty acid and alpha-cyclodextrin are present in the complex in a ratio selected from the group consisting of 3 mol of alpha-cyclodextrin: 1 mol of an essential fatty acid, 4 mol of alpha-cyclodextrin: 1 mol of an essential fatty acid, and a mixture of these complexes.

9. A process for preparing a preparation as claimed in claim 1, comprising

dispersing a complex of vitamin F and alpha-cyclodextrin in water to form a dispersion; and

then mixing the dispersion into a lipophilic part of an emulsion.

APPENDIX B

Appendix B: Evidence Presented

Attached is the power point presentation submitted with the Response to the Final Office Action.

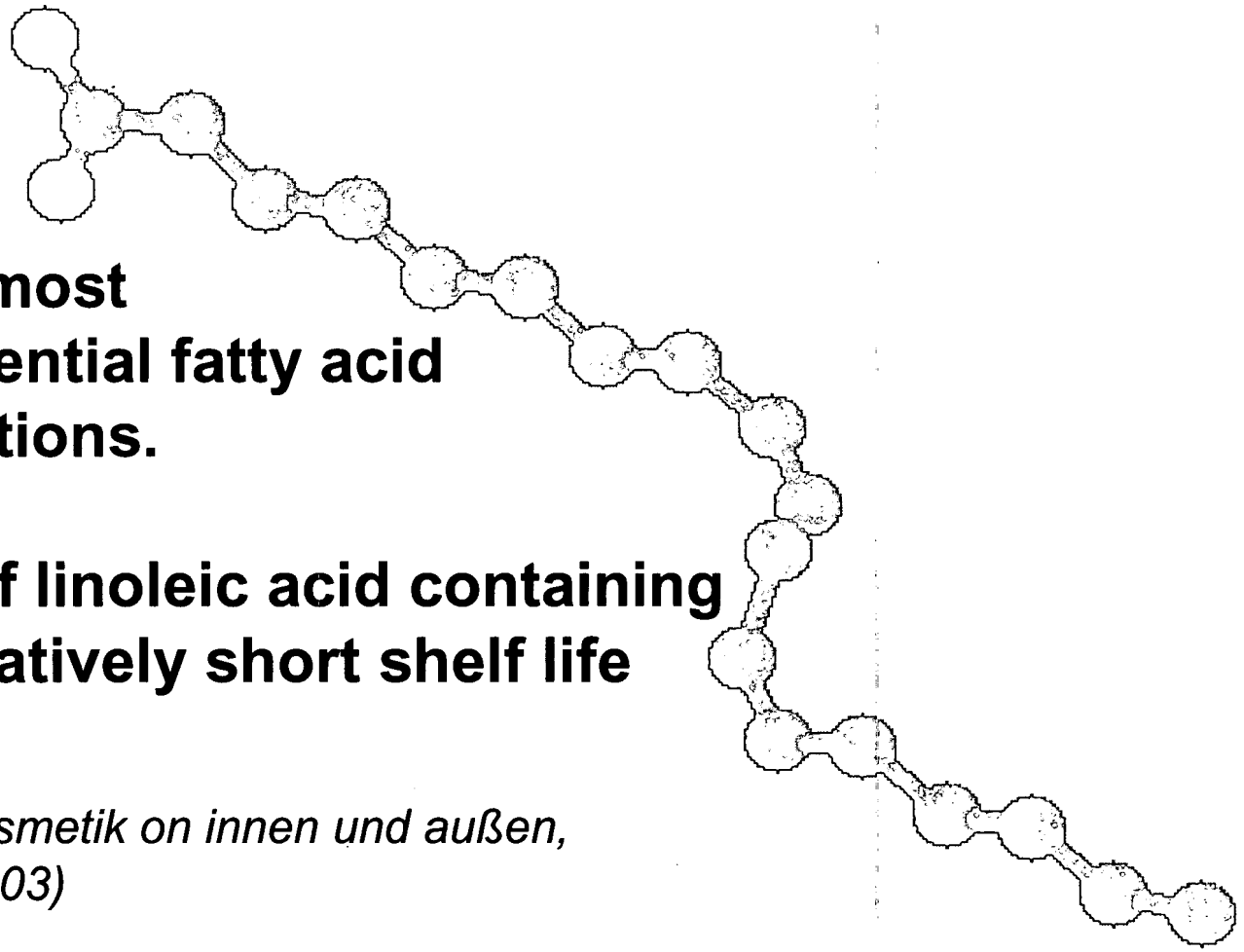
WACKER FINE CHEMICALS

CYCLODEXTRINS ANOTHER TOOL FOR ENCAPSULATION OF LINOLEIC ACID

Regiert Marlies, Kupka Michaela, Sigl Harald, F-I-P, March 2005

CREATING TOMORROW'S SOLUTIONS

LINOLEIC ACID, $C_{17}H_{31}COOH$, E.G. (Z,Z)-9,12-OCTADECADIENOIC ACID

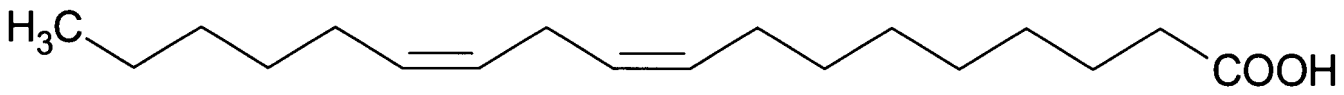


Linoleic acid is the most frequently used essential fatty acid in cosmetic formulations.

One disadvantage of linoleic acid containing oils is there comparatively short shelf life

(Essenzielle Fettsäuren - Kosmetik on innen und außen, Dr. Hans Lautenschläger, 2003)

FUNCTION, PHYSIOLOGICAL EFFECTS



- Belongs to the group of omega-6 fatty acids
- It cannot be synthesized by animals
- Linoleic acid is incorporated in the skin to the most important barrier-active "ceramide I"
  (Essenzielle Fettsäuren - Kosmetik von innen und außen, Dr. Hans Lautenschläger, 2003)
- Is essential for the human body

FUNCTION, PHYSIOLOGICAL EFFECTS

- Is important for the synthesis of eicosanoids, which have a regulatory action in various tissues

  (Technical Information BASF, „products for the food and pharmaceutical industry", 2002)

- A lack of linoleic acid in the skin has e.g. the effect of:
  - barrier disruption of the skin
  - a higher rate of the trans-epidermal water-loss
  - the skin becomes dry, scale and gets a unhealthy colour

- Acts both as a concentrated energy carrier and as a starting material for the synthesis of arachidonic acid (important component of cell membranes)

  (Technical Information BASF, „products for the food and pharmaceutical industry", 2002)

FUNCTION, PHYSIOLOGICAL EFFECTS

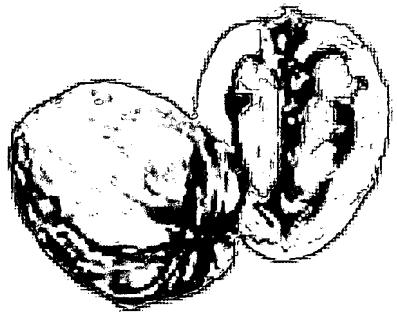
- Requirements / intake recommendations:
  the adult requirement of linoleic acid is 8 – 10g per day
- There is an increased requirement for essential fatty acids after severe accidents and in certain diseases

PROPERTIES AND OCCURRENCE

- Is a colorless to straw colored liquid
- Insoluble in water, soluble in oil and fats
- Is the most common polyunsaturated fatty acid
- Linoleic acid also may convert to a isomeric unsaturated conjugated fatty-acid
- It is easily oxidized by air to peroxides that have undesirable biological effects
- Vegetable oils become rancid when exposed to air at room-temperature and can seriously spoil the taste, odor and stability of food products
- It is found in nature in plants and animal tissues

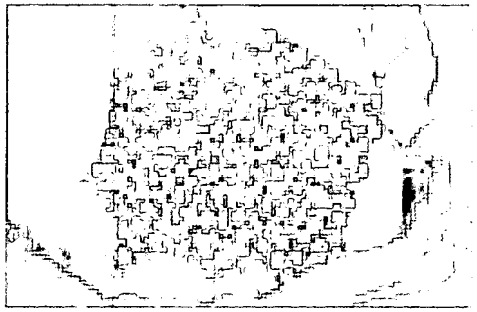
OCCURRENCE

walnut



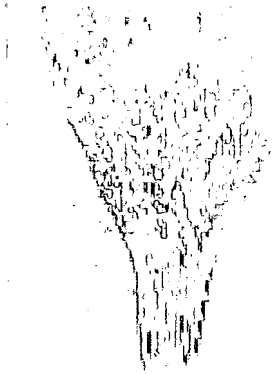
peanut

soya

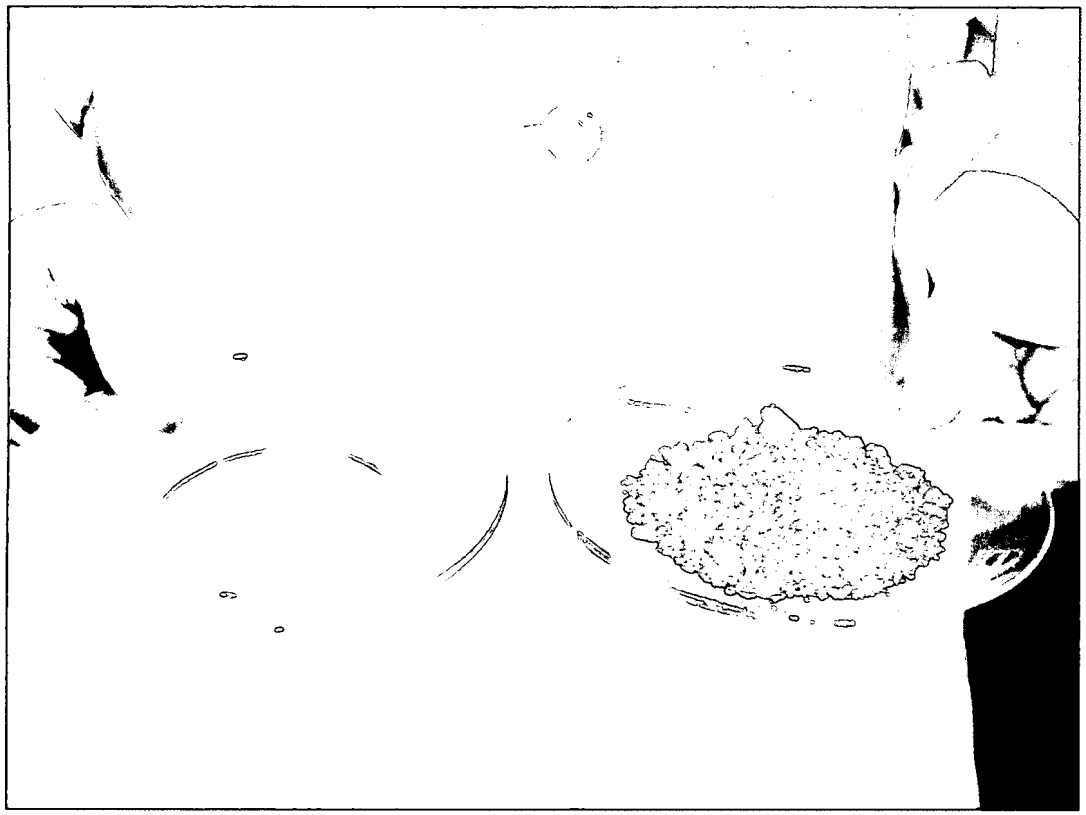


seeds of sunflower

corn



CONVERSION FROM LIQUID TO SOLID COMPLEX



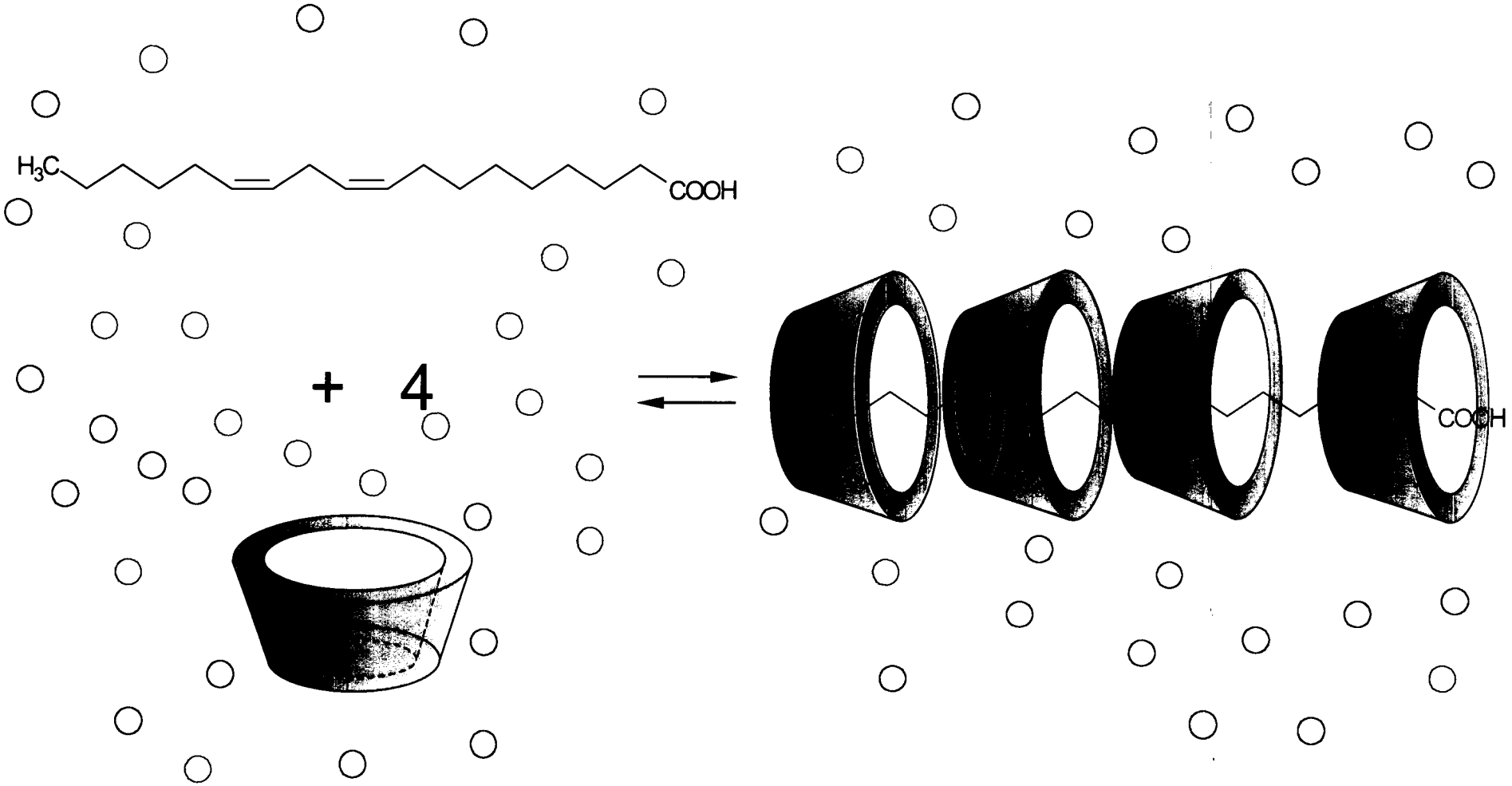
Left:
pure linoleic acid

Right:
CAVAMAX®W6/LINOLEIC ACID-COMPLEX

APPLICATION

- As component in cosmetic formulations like
  - emulsion, cream
  - gel
  - lip-balm
- Colour cosmetic, like lip-stick
  - face powder
  - eye shadow
  - face mask
- As component in derma products
  linoleic acid helps to cure
  - skin disease
  - sun burn
  - burns
  - akne vulgaris

SCHEMATIC REPRESENTATION OF AN INCLUSION COMPLEX FORMATION BETWEEN CYCLODEXTRIN AND LINOLEIC ACID



CAVAMAX® W6/LINOLEIC ACID-COMPLEX, CHARACTERISTICS

	CAVAMAX®W6-Complex
appearance:	white granulate/powder
active content:	min. 7.5 % (NMR, GC)
water content:	max. 14%
INCI names	cyclodextrin/linoleic acid
patent pending	DE10253042.4-4; EP03026137.4; JP 2003-385675; KR 2003-0077579

BENEFITS OF CAVAMAX® W6/ LINOLEIC ACID -COMPLEXES BY APPLICATION IN FORMULATIONS

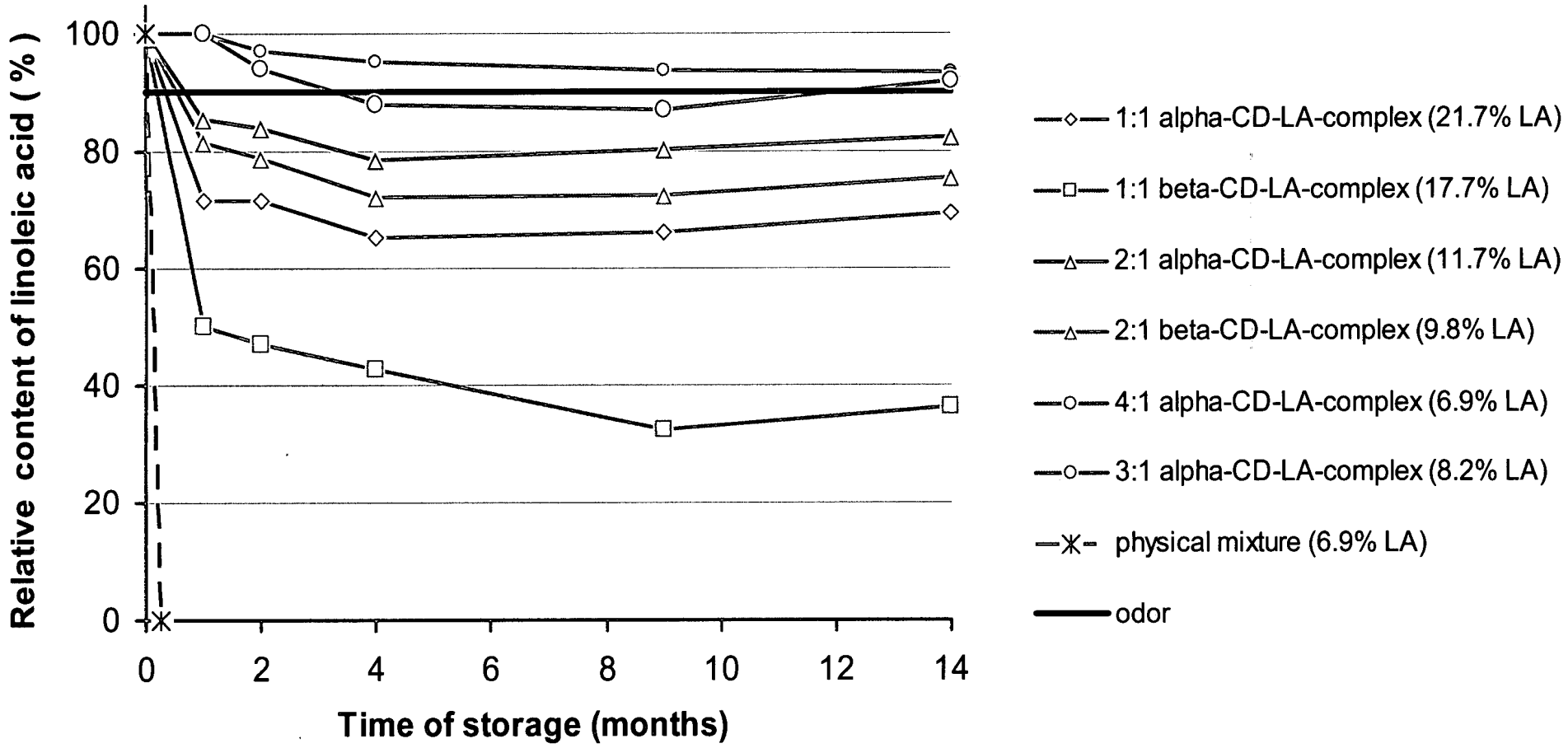
- Improved stability of linoleic acid e.g. oxygen, UV-A and UV-B and temperature
- Controlled release
- No rancidness in finished products e.g. during application
- No need of a stabiliser in cosmetic formulations
- Preparation of cosmetic formulations is even possible at higher temperatures
- Easy handling

BENEFITS OF CAVAMAX® W6/ LINOLEIC ACID-COMPLEXES BY APPLICATION IN FORMULATIONS

- Stable dispersion/emulsion
- Increase of texture of emulsions
- Efficient depot system
- Positive costs/benefit-factor
- Recommended dosage:
  0.5 - 15% of CAVAMAX®W6/LINOLEIC ACID-COMPLEX
- In food products: improved taste and odor stability

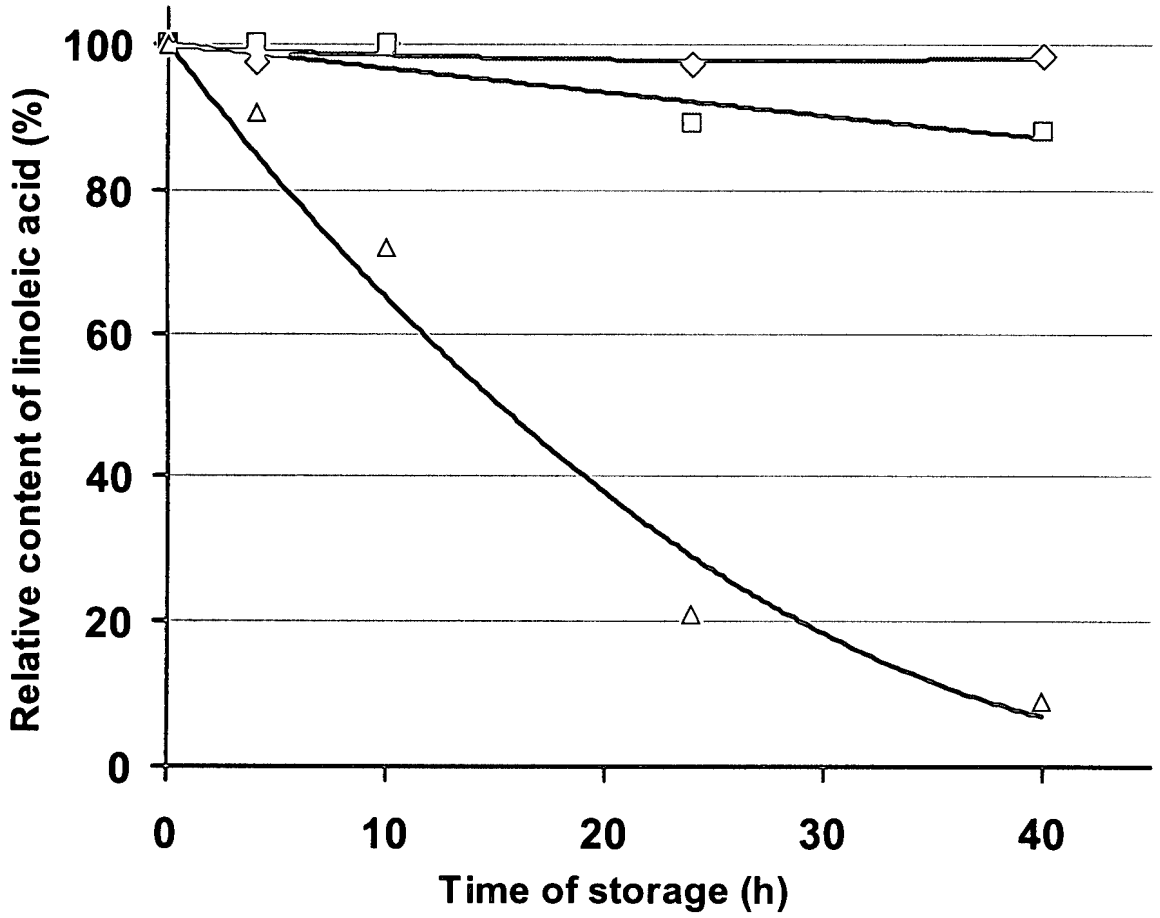
THERMOSTABILITY OF CAVAMAX®/LINOLEIC ACID-COMPLEXES WITH VARIOUS MOLAR RATIO OF ACTIVE AT 45°C

Stability at 45°C, stored in open vessels (90 mm diameter, 3 mm layer)



UV-STABILITY OF COMPLEXED AND UNCOMPLEXED LINOLEIC ACID IN GEL

Stability in Sun Screen Softgel (1.0 % linoleic acid. "suntest" UV-A and UV-B, 45 °C)



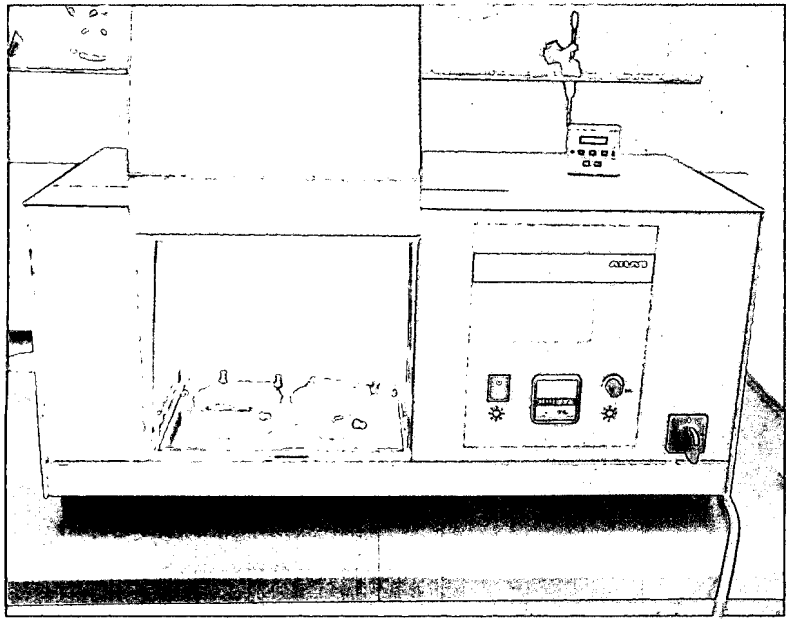
◇ Softgel + 4:1-alpha-cyclodextrin-linoleic acid-complex

□ Softel + 3:1-alpha-cyclodextrin-linoleic acid-complex

△ Softgel + linoleic acid uncomplexed

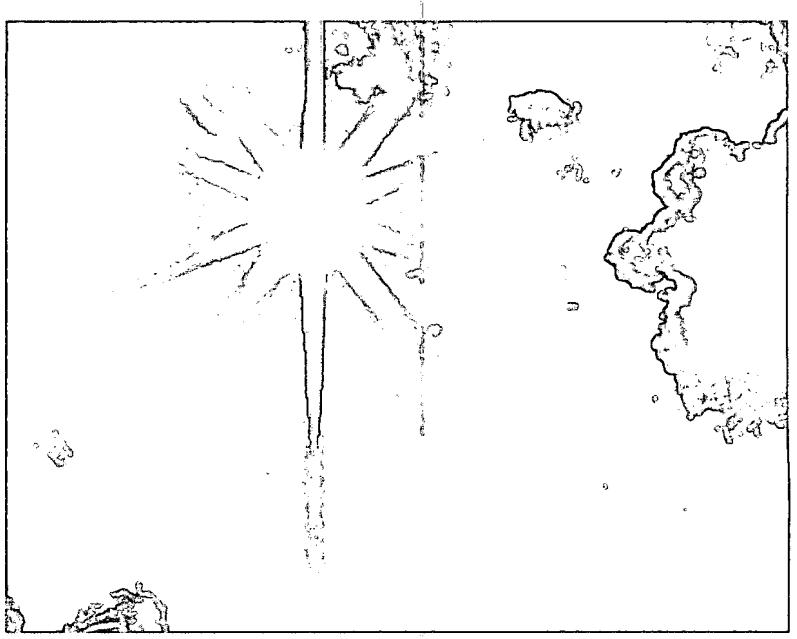
UV-STABILITY TEST IN SUN-TEST DEVICE: COMPARISON

SUN-Test device



max. irradiation/day = 66 MJ/m²

"Sun-Bathing"



irradiation/day (middle europe) = 5.7 MJ/m²

ratio (time lapse factor) =

11 : 1

UV-A AND UV-B STABILITY TEST IN SUN-TEST EQUIPMENT

Method

Equipment	SUNTEST CPS from ATLAS
Radiation-source	Xenon-Lampe
Optical filter	Solar Standard (filter referring to **COLIPA*** and DIN 67501)
Air cooled sample room	max. determined inside-temperature = 45°C
Maximum radiance	E (300nm – 800nm) = 765W/m²
Constant controlling of the Irradiation	via photodiode

(source: ATLAS-Material Testing Solutions)

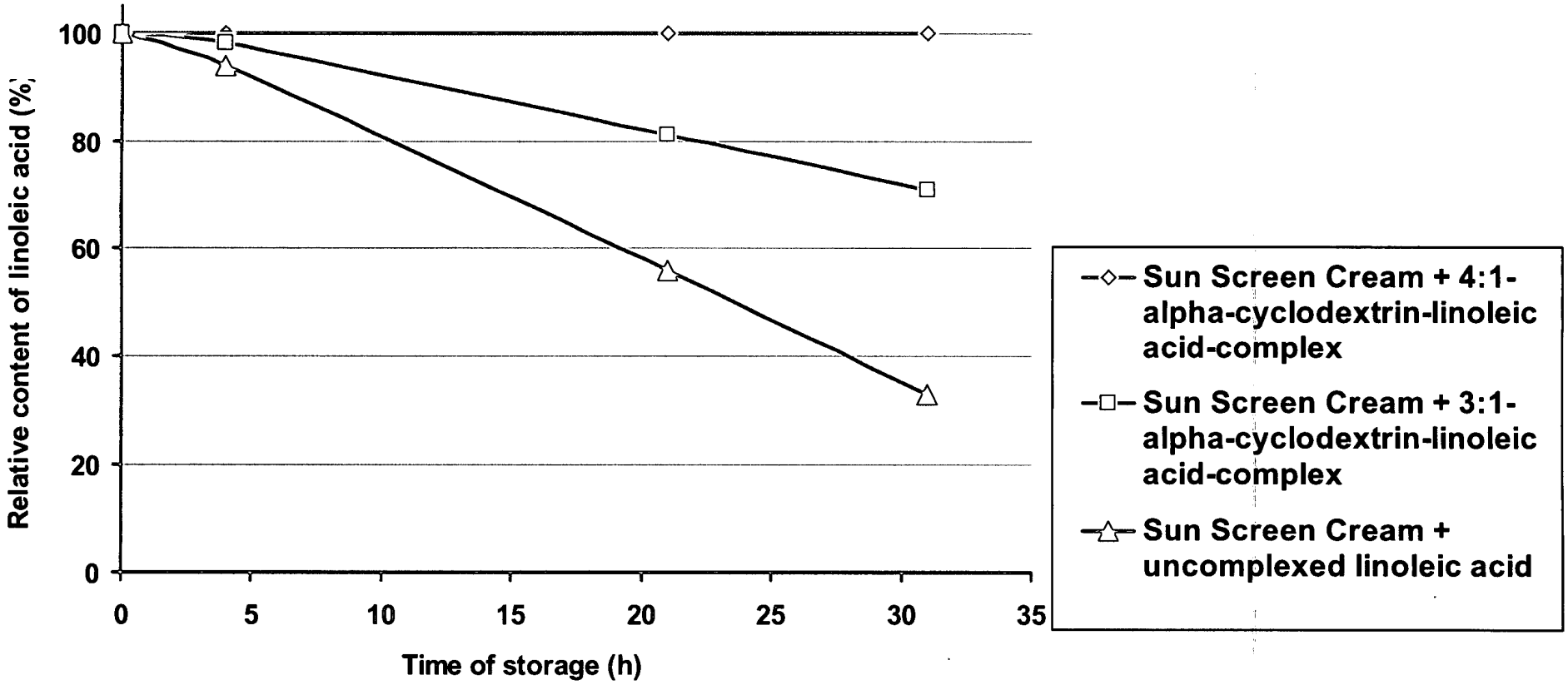
Sample preparation

Solid substance like cyclodextrin-complex
3 – 4 g substance between 2 layers of glass 10 x 10 cm
(glass rim has to be covered with an adhesive tape)

Soft substance like creams und pastes
3 – 4 g in a PE-plastic bag 10 x 10 cm (melted rim)

UV-STABILITY OF COMPLEXED AND UNCOMPLEXED LINOLEIC ACID IN CREAM

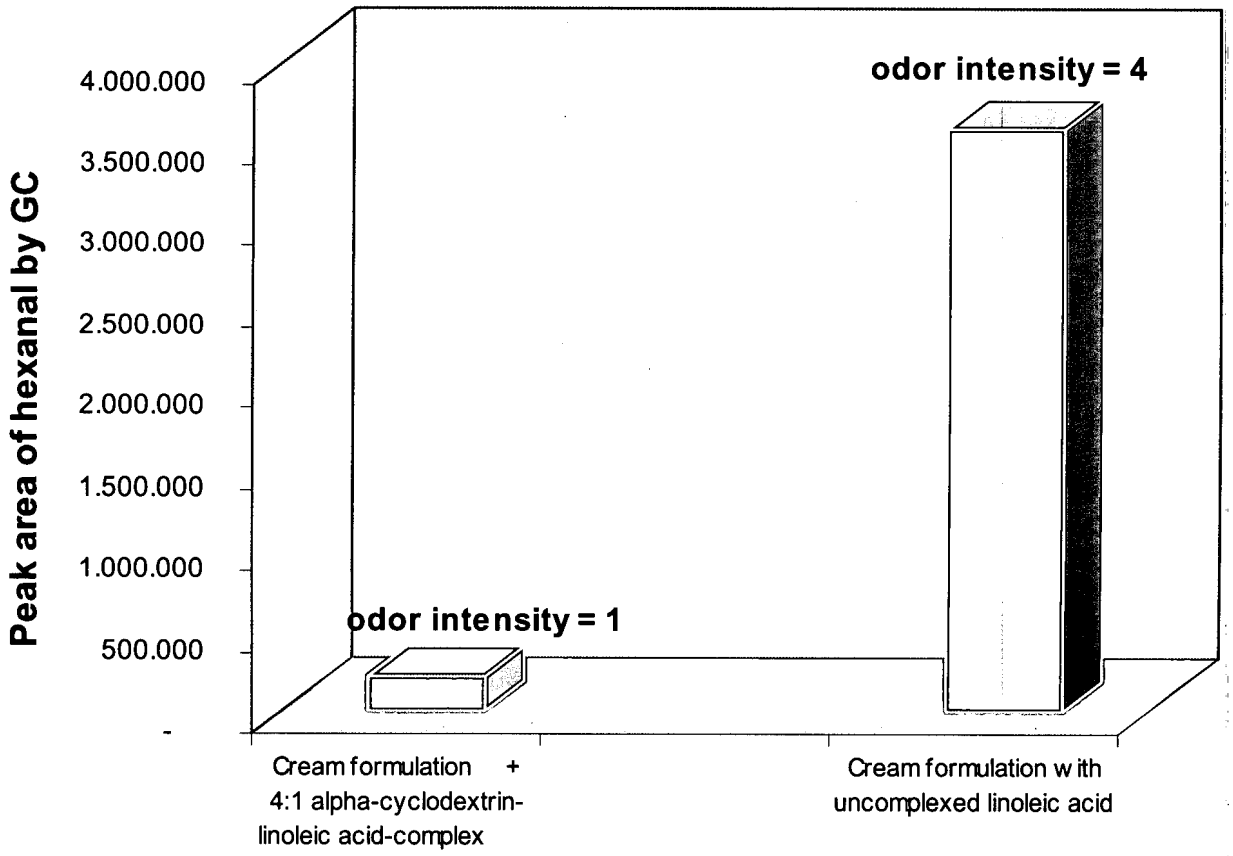
Stability in Sun Screen Cream
(1.0 % linoleic acid content, "suntest" UV-A and UV-B, 45 °C)



LONG-TERM STABILITY OF 1% LINOLEIC ACID AS 4:1-ALPHA-CD/LA-COMPLEX AND UNCOMPLEXED IN CREAM

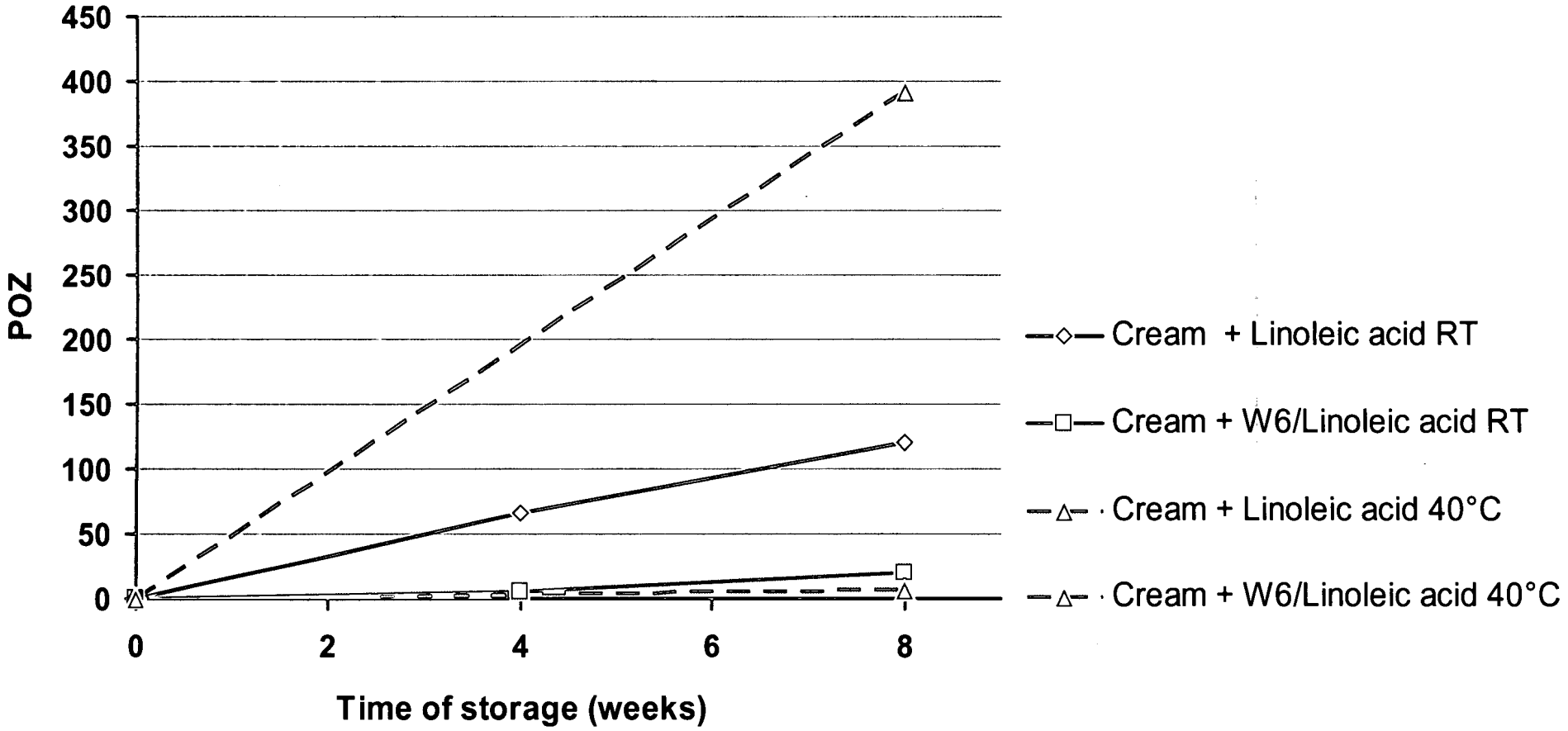
at room temperature after 12 months storage.

Sensory- and SPME/GC-Analysis of deteriorated linoleic acid e.g. as Hexanal



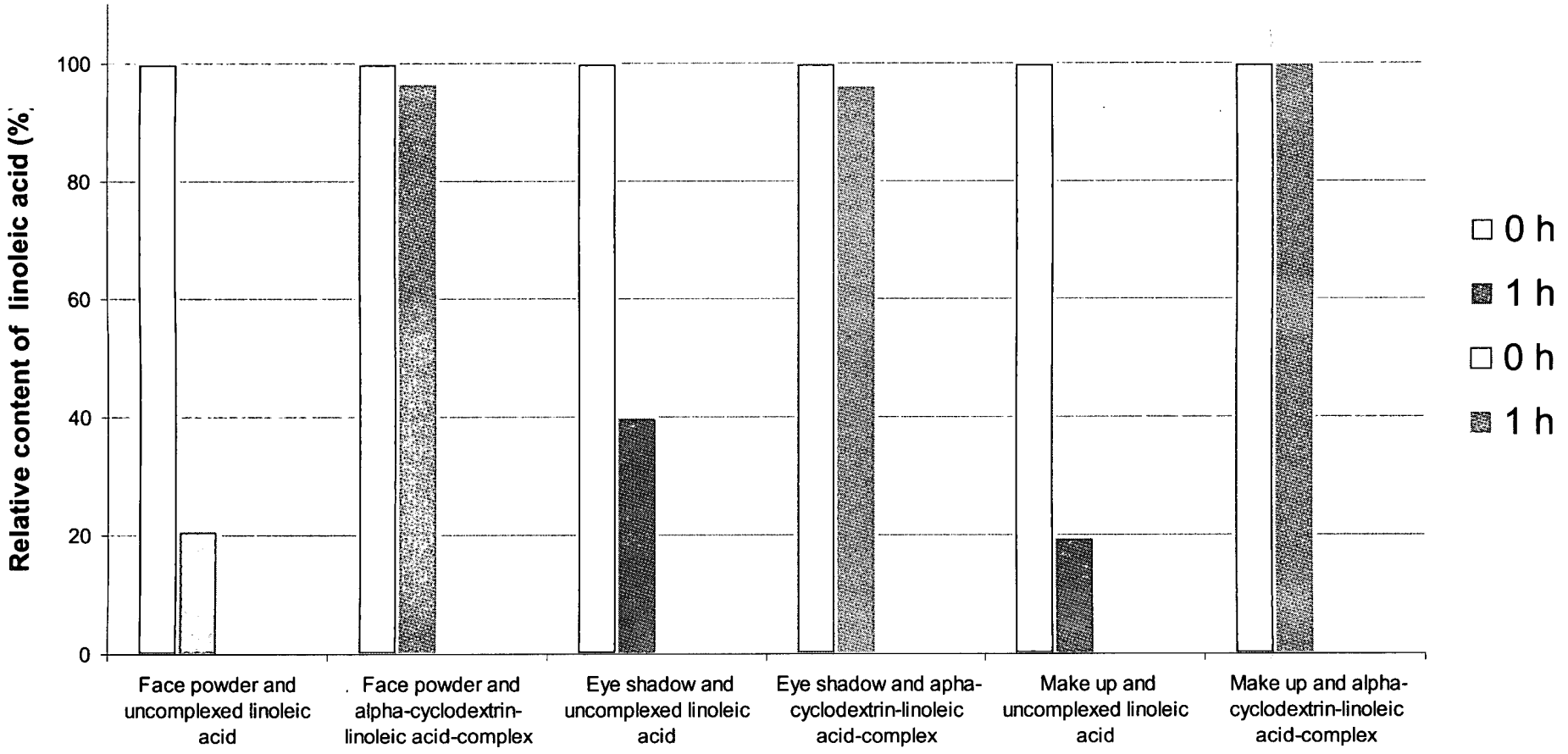
DEGRADATION OF COMPLEXED AND UNCOMPLEXED LINOLEIC ACID BY PEROXIDE VALUE

Instability in Cream W/O stored at different temperatures, (1.0% linoleic acid content) determined by peroxide value



GHT-STABILITY OF 1% LINOLEIC ACID AS 4:1-ALPHA-CD/LA-OMPLEX AND UNCOMPLEXED IN COLOR-COSMETICS

"Sun-Test" UV-A and UV-B at 45 °C; GC-Analysis of Linoleic Acid-Content



DETERMINATION OF LINOLEIC ACID IN CYCLODEXTRIN AND COSMETIC PRODUCTS

Analytical Method

Principle of the Method:	Silylation by MSHFBA, GC-Direct Injection, Internal Standard
Name of the analyte :	Linoleic Acid
Retention times (min) :	Analyte (Linoleic Acid) 8,71 Int.Std. (Eicosanoic Acid) 10,21
Sample name, matrix:	Cyclodextrin or Cosmetic Products
Solvent:	Solvent-Mix 80 % v/v Pyridine + 20 % v/v THF
Quantitation - method :	Internal Standard ISTD
INTERNAL Standard:	Eicosanoic Acid (C20) CAS - NR.: [530-30-9]

Internal Standard solution

Prepare a concentrated (e.g. about 1100 ppm) stock solution of Eicosanoic Acid in the solvent mix. Add a small volume (about 0.8 g) of that stock solution to (about 5g) of the Silylating Reagent MSHFBA to get a ISTD-working solution:
150 ppm ISTD in (MSHFBA > 95 %, < 5% solvent mix).

DETERMINATION OF LINOLEIC ACID IN CYCLODEXTRIN AND COSMETIC PRODUCTS

Sample preparation:

Dissolve the sample (Cyclodextrin 0.1 %, Cosmetic Products 1 %) in the solvent mix (rise in temperature, short ultrasonic agitation).

Silylating Reaction:

200 mg of the sample solution are diluted with 700 mg THF + 100 mg ISTD-working solution = 1000 mg reaction solution with 15 ppm ISTD. Heat the reaction mixture (70 °C, about 15 min) --- Alu Block Heater.

DETERMINATION OF LINOLEIC ACID IN CYCLODEXTRIN AND COSMETIC PRODUCTS

Calibration Range:

Analyte: 5 to 20 mg/kg solvent
ISTD: 15 mg/kg solvent

Calibration solutions:

Prepare solutions of linoleic acid and eicosanoic acid in the pyridine/THF-solvent mix separately and store them in a refrigerator (< 1 month, without silylation).
Dilute and mix the separate solutions to get >= 5 linoleic acid-calibration levels within the calibration range 5-20 ppm with constant 15 ppm ISTD-concentration for all levels.
Silylating Reaction:
Add 10 % (w / w) of the silylating reagent to the calibration solutions. Heat the calibration mixtures (70°C, about 15 min) --- Alu Block Heater.

Reagents:

THF p.A.
Pyridine
MSHFBA, N-Methyl-N-trimethylsilylheptafluorbutyramid (Macherey-Nagel)

DETERMINATION OF LINOLEIC ACID IN CYCLODEXTRIN AND COSMETIC PRODUCTS

GC - Operating Conditions

Instrument:	Gaschromatograph HP 6890 equipped with FID and autosampler			
Column:	30 m x 0. 32 mm ID fused silica capillary column			
Stationary phase:	HP-5 Methyl-Polysiloxan with 5 % Phenyl-Polysiloxan			
Film Thickness:	df = 0,23 µm			
Supplier :	Agilent			
Column temperature:				
Temp. program :	Initial temp.	60 °C	Initial Time	1. 0 min
	Program Rate A	30 °C / min	Program Rate B	- °C / min
	Final Temp.	250 °C	Final Temp.	- °C
	Final Hold Time:	7.0 min	Final Hold Time:	- min
	Analysis Time:	min		
Carrier gas:		Helium		
Column Head Pressure:		117 kPa		
Flow Rate:		1,5 ml / min		
Electronic pressure control:		Constant Pressure		
Injection:		Direct Injection with autosampler HP 7673 A, Splitless mode		

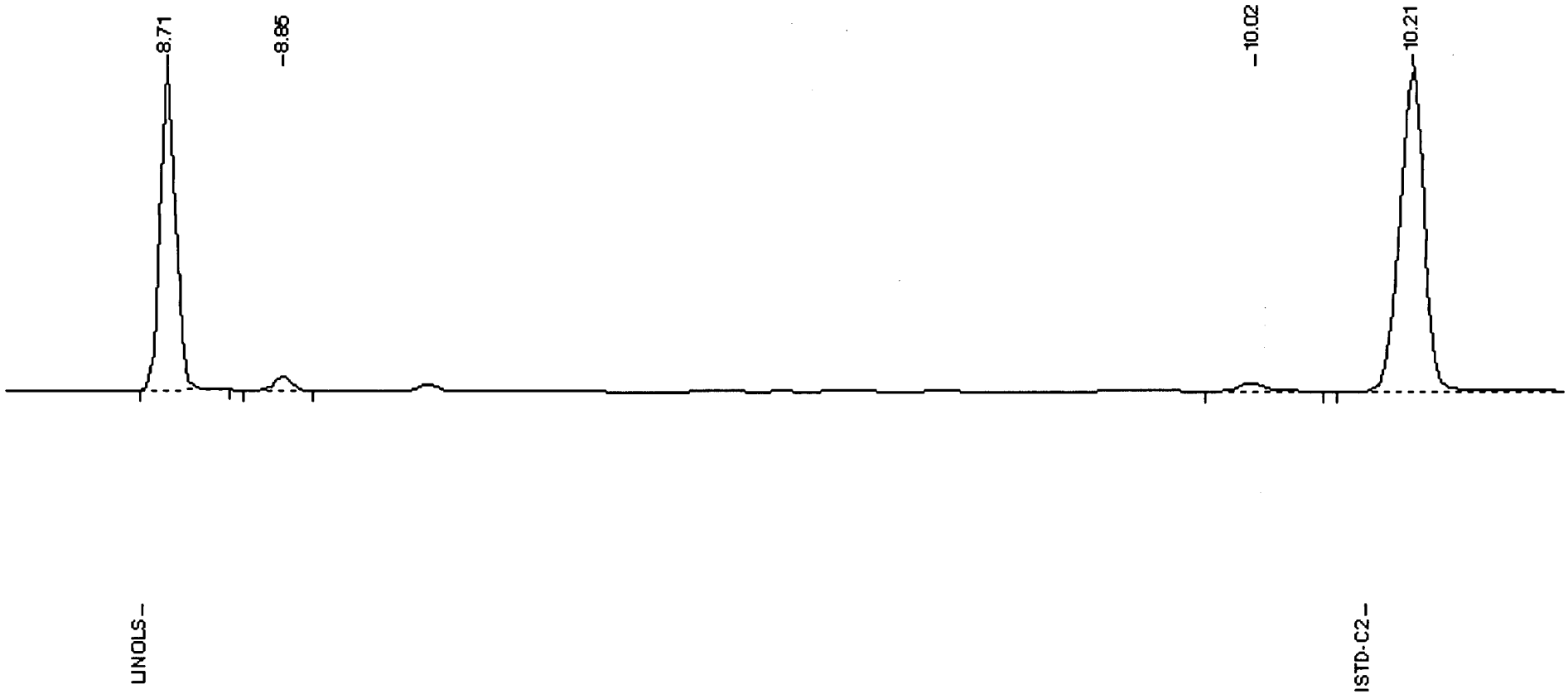
DETERMINATION OF LINOLEIC ACID IN CYCLODEXTRIN AND COSMETIC PRODUCTS

Inject samples:	Silylation reaction mixture of the calibration solutions and of the sample solution, respectively.		
Injektionvolume (µL):	1		
Inlet:	Split/Splitless capillary inlet with EPC		
Temperature:	300 °C		
Split Flow:	100 ml / min	Purge B off Purge B on	0 min 0,9 min
Septum Purge :	3-5 ml / min		
Detector:	FID	Temperature 300°C	
Hydrogen:	40 ml/min		
Air :	450 ml/min		
Make up gas:	Helium 29 ml/min		
Data acquisition and quantitation software:	PE Turbochrome		
Appendix:	Representative chromatogram		
Representative GC-Run:	Linoleic acid with Int. Standard Eicosanoic Acid after Silylation		

DETERMINATION OF LINOLEIC ACID IN CYCLODEXTRIN AND COSMETIC PRODUCTS

Representative GC-Run:

Linoleic Acid with Internal Standard Eicosanoic Acid after Silylation



PREPARATION OF A SUN SCREEN SOFT STICK WITH (0.30 W/W%) LINOLEIC ACID

	Ingredients	INCI-Names	w/w	Supplier
A)	Vaseline	Petrolatum	68,9%	
	Wacker Belsil® SDM 6022	Stearoxy Dimethicone, Dimethicone	25,0%	Wacker-Chemie AG
B)	CAVAMAX®W6/LINOLEIC ACID-COMPLEX (7.4% linleic acid)	Cyclodextrin/Linoleic acid	4,0%	Wacker-Chemie AG
	Parsol 1789	Butyl Methoxydibenzoylmethane	2,0%	Givaundan
	Kathon CG	Methylchloroisothiazolinone , Methylisothiazilinone	0,1%	Rohm&Haas
			100,0%	

PREPARATION OF A SUN SCREEN SOFT STICK WITH (0.30 W/W%) LINOLEIC ACID

Calculation:

7.4g linoleic acid are related to 100g complex, 0.296g Linoleic acid related to x g complex

$$\frac{100g \times 0.296g}{7.4g} = 4.0g$$

Preparation:

Heat A to approx. 60°C and mix well, add B at approx. 45°C under stirring for about 15 minutes.

The content of linoleic acid in the formulation is detected by GC.

PREPARATION OF A SUN SCREEN SOFT GEL WITH (0.30 W/W%) LINOLEIC ACID

	Ingredients	INCI-Names	w/w	Supplier
A)	Water, dd	Aqua	86,8%	
	CAVAMAX®W6/LINOLEIC ACID-COMPLEX (7.4% linoleic acid)	Cyclodextrin/linoleic acid	4,0%	Wacker-Chemie AG
	Carbopol 940	Carbomer 940	2,5%	Noveon
	Wacker Belsil® PDM 20	Phenyl Trimethicone	4,5%	Wacker-Chemie AG
	Parsol MCX	Ethylhexyl Methoxycinnamate	2,0%	Givaudan
	Kathon CG	Methylchloroisothiazolinone, Methylisothiazilinone	0,20%	Rohm&Haas
			100,0%	

PREPARATION OF A SUN SCREEN SOFT GEL WITH (0.30 W/W%) LINOLEIC ACID

Calculation:

7.4g linoleic acid are related to 100g complex, 0.296g Linoleic acid related to x g complex

$$\frac{100g \times 0.296g}{7.4g} = 4.0g$$

Preparation:

Mix all ingredients at approx. 40°C.

The content of linoleic acid in the formulation is detected by GC.

PREPARATION OF A SUN SCREEN CREAM WITH (0.30 W/W%) LINOLEIC ACID

	Ingredients	INCI-Names	w/w	Supplier
A)	Water, dd	Aqua	60,7%	
	CAVAMAX®W6/LINOLEIC ACID-COMPLEX (7.4% linoleic acid)	Cyclodextrin/linoleic acid	4,0%	Wacker-Chemie AG
	Carbopol 934 Polymer (1% solution)	Carbomer	5,0%	Noveon
	Tetrasodium EDTA	Tetrasodium EDTA	0,20%	
	Glycerine	Glycerine	2,5%	
	Triethanolamine	Triethanolamine	1,0%	
B)	Wacker Belsil® DM 350	Dimethicone	2,0%	Wacker-Chemie AG
	Isopropyl Myristate	Isopropyl Myristate	9,0%	
	Stearyl Alkohol	Stearyl Alkohol	9,5%	
	Cetyl Alkohol	Cetyl Alkohol	0,50%	
	Stearic Acid	Stearic Acid	3,0%	
	Sodium Stearat	Sodium Stearat	1,0%	
	Parsol MCX	Ethylhexyl methoxycinnamate	1,5%	Givaundan
C)	Kathon CG	Methylchloroisothiazolinone, Methylisothiazilinone	0,10%	Rohm&Haas
			100,0%	

PREPARATION OF A SUN SCREEN CREAM WITH (0.30 W/W%) LINOLEIC ACID

Calculation:

7.4g linoleic acid are related to 100g complex, 0.296 g linoleic acid related to x g complex

$$\frac{100\text{g} \times 0.296\text{ g}}{7.4\text{ g}} = 4.0\text{ g}$$

Preparation:

- mix the components of phase A) at 70°C
- mix the components of phase B) at 70°C
- than pour phase A) in phase B) under intense stirring
- after cool down to 45°C add finally phase C)

The content of linoleic acid in the formulation is detected by GC as described

PREPARATION OF A BELSIL FOUNDATION WITH (0.30 W/W%) LINOLEIC ACID

	Ingredients	INCI-Names	w/w	Supplier
A)	Wacker Belsil® DM 1 plus	Dimethicone	10,00%	Wacker-Chemie AG
	Wacker Belsil® CM 7026 VP	C26-28 Alkyl Methicone	2,70%	Wacker-Chemie AG
	Wacker Belsil® SPG 128 VP	Cyclopentasiloxane and Caprylyl Dimethicone Ethoxy Glucoside	11,0%	Wacker-Chemie AG
	Wacker Belsil® DM 5	Cyclomethicone	2,30%	Wacker-Chemie AG
	Hostacerin DGI	Polyglyceryl-2 Sesquiisostearate	2,40%	Clariant
	Wacker Belsil® TMS 803	Trimethylsiloxysilicate	1,50%	Wacker-Chemie AG
B)	Mixture of ferricoxide and titaniumoxide		8,50%	
	Talc	Talc	5,00%	Grolman
C)	Water, dd	Aqua	50,2%	
	Sodium chloride	Sodium Chloride	2,00%	Merck
	CAVAMAX®W6/LINOLEIC ACID-COMPLEX (7.4% linoleic acid)	Cyclodextrin / linoleic acid	4,00%	Wacker-Chemie AG
D)	Fragrance	Perfume	0,30%	
	Kathon CG	Methylchloroisothiazolinone, Methylisothiazilinone	0,10%	Rohm&Haas
			100,0%	

PREPARATION OF A BELSIL FOUNDATION WITH (0.30 W/W%) LINOLEIC ACID

Calculation:

7.4g linoleic acid are related to 100g complex, 0.296 g linoleic acid related to x g complex

$$\frac{100\text{g} \times 0.296\text{ g}}{7.4\text{ g}} = 4.0\text{ g}$$

Preparation:

- mix the components of phase A) at 75°C
- mix the components of phase B) and add to A) under intense stirring
- disperse the complex in phase C) at 50°C
- than pour slowly phase C) to the mixture of phase A) and B)
- after cool down to 45°C add finally phase D)
- than stir till the mixture is homogenous

The content of linoleic acid in the formulation is detected by GC

SUPPLEMENTS

- Page 27, 28, 29, 30, 31, 32 ,33 and 34 on 15.03 2006, adapted formulation recipe
- Page Wacker AG 27, 29, 31 ,33 on 10.08.2006, adapted formulation recipe
- Page 18 revaised
- Page 33 and 34 revaised

CAVAMAX®W6/LINOLEIC ACID - COMPLEX

Consumer expect just high-quality skincare products with extraordinary performance

APPENDIX C

Appendix C: Related Appeals and Proceedings

None